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10/829,079	04/22/2004	Stephen Bennett Elliott		6024

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Stephen Bennett Elliott
702 Buffalo Springs Drive
Allen, TX 75013

EXAMINER

KAHELIN, MICHAEL WILLIAM

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3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,079	Applicant(s) ELLIOTT, STEPHEN BENNETT	
	Examiner Michael Kahelin	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-43 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28, 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 19-28 and 39-43 have been considered but are moot in view of the new ground(s) of rejection. Applicant argued that Kullok does not determine whether an average heartbeat of a patient is stable before providing movement signals because Kullok discloses that "about 2 minute is [sic] required to obtain a relatively stable heart beat" (col. 4, line 2), yet teaches of an embodiment of the invention wherein a delay period is used that comprises only about a 30 second delay (col. 44, line 28). However, Kullok indicates, "the present invention is not limited to an initial series of 27 intervals" (col. 44, line 17), but, "other numbers...may be used as long as the number conforms to the above stated logic" (col. 4, line 17). Referring to the bottom of column 43, "the above logic" is delaying the first movement signal until after the expiration of a delay period comprising a number of "previously and preferably unperturbed [i.e., stable] RR intervals". So although, Kullok may or may not disclose an embodiment wherein the delay period is less than the 2 minutes disclosed as being required to obtain a relatively stable heart rate, Kullok also discloses an embodiment that does determine that the cycle is stable before providing the movement signal (at 1608).
2. Applicant further argued that neither Vaschillo nor Kullok teach of providing a first signal to indicate when a subject should inhale and a second signal to indicate when to exhale. Examiner maintains the position of the previous Office Action (paragraph 6

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below) that these signal are provided to a subject by virtue of the HRV and respiratory signals being provided to a subject, along with the instructions to produce a zero phase shift between the two signals. As such, the minima and maxima of the HRV signal are the first signal to indicate when a subject should inhale and a second signal to indicate when to exhale because, if inhalation and exhalation are initiated based on these signals, coherence between the HRV and respiratory cycles will be achieved.

3. Applicant further argued that Kullok does not promote synergy between movement and physiological activity, but only randomizing the signal. However, as the title, abstract, and column 4, line 30 indicate, Kullock's invention is intended to provide synergistic coupling between a movement and physiological signal.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 19-28 and 39-43 are rejected under 35 U.S.C. 103(a) as obvious over Vaschillo et al. (US 5,997,482, hereinafter "Vaschillo") in view of Kullok et al. (US 6,644,976, hereinafter "Kullok"). Vaschillo discloses the essential features of the claimed invention including the following:

6. In regards to claim 19-26, Vaschillo discloses a method comprising monitoring a heartbeat, determining a heart rate variability cycle, detecting positive and negative

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heart rate peaks, providing an exhale signal at the positive heart rate peak and an inhale signal at the negative heart rate peak (Fig. 3A and col. 3, lines 23-52). Please note that, because the subject is instructed to ensure that there is a zero phase shift between the HRV tracing and respiratory tracing, the subject performs the method of detecting the positive and negative peaks and the device provides the inhale and exhale signals by virtue of the patient seeing the tracings in Figure 3A and exhaling at the peak of the HRV cycle. In other words, the inhale and exhale signals are the peaks of the HRV cycle because the subject is instructed to match the phase angle of the two (cardiac and respiratory) tracings. Vaschillo does not disclose performing the above tasks in response to determining that the heartbeat rate is stable, instructing the subject to obtain a stable HRV cycle before beginning exercise, providing an exercise tempo signal based on HRV, or disabling the inhale/exhale signals when transitioning from a first tempo to a second tempo. Kullok teaches of providing movement tasks in synergy with physiological activity in response to determining that the heartbeat rate is stable (col. 43, line 62-col. 44, line 21, i.e., determination that the heartbeat is stable is synonymous with a determination that the "initial interval" has expired), instructing the subject to obtain a stable HRV cycle before beginning exercise (col. 44, line 2) to allow accurate, stable measurement of the heart rate parameter; providing an exercise tempo signal (abstract) to promote or improve performance in various activities (col. 1, line 11); and allowing the heart to stabilize when transitioning from a first tempo to a second tempo (col. 44, line 2) to avoid providing inaccurate movement signals to the subject. Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify Vaschillo's invention by instructing the subject to obtain a stable HRV cycle before beginning exercise to allow accurate, stable measurement of the heart rate parameter; providing an exercise tempo signal to promote or improve performance in various activities; disabling the breathing signal when transitioning from a first tempo to a second tempo to avoid providing inaccurate breathing signals to the subject.

7. In regards to claim 27, Vaschillo discloses that the signal is a visual signal (Fig. 2).

8. In regards to claim 28, Vaschillo discloses that the inhale and exhale signals correspond to a cycle that is coherent (zero phase lag) with the HRV signal (col. 3, line 41).

9. In regards to claims 39-43, Vaschillo discloses the essential features of the claimed invention except for instructing a subject to synchronize body movement with inhaling and exhaling; determining that a subject is transitioning from a first level of exercise to a second level in response to an unstable variability cycle; disabling the inhale and exhale signals in response to a transition between exercise levels; or determining the stability, detecting heart rate peaks, and providing respiratory signals for a second heart rate variability cycle. Kullok teaches of instructing a subject to synchronize body movement with inhaling and exhaling (abstract) to provide a synergistic effect between the physiological activity and voluntary movement (title); determining that a subject is transitioning from a first level of exercise to a second level in response to an unstable variability cycle (col. 44, line 2, i.e. Kullok teaches that

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change in physical activity will result in an unstable heart beat variability cycle) to provide a synergy movement signal of a frequency related to the physiological signal and is thusly therapeutically effective; disabling the movement signals in response to a transition between exercise levels (col. 44, line 30; the "synergistic engine" does not supply movement signal until expiration of the "initial interval") to allow an accurate and stable physiological signal to be determined before providing the subject with instruction to alter their movement; and determining the stability, detecting heart rate peaks, and providing respiratory signals for a second heart rate variability cycle (col. 44, line 5; Kullok discloses that the method described in Figure 16 is repeated several times) to allow the method to be applied to various levels of activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vaschillo's invention by instructing a subject to synchronize body movement with inhaling and exhaling to provide a synergistic effect between the physiological activity and voluntary movement; determining that a subject is transitioning from a first level of exercise to a second level in response to an unstable variability cycle to provide a synergy movement signal of a frequency related to the physiological signal and is thusly therapeutically effective; disabling the movement signals in response to a transition between exercise levels to allow an accurate and stable physiological signal to be determined before providing the subject with instruction to alter their movement; and determining the stability, detecting heart rate peaks, and providing respiratory signals for a second heart rate variability cycle to allow the method to be applied to various levels of activity.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GE
GEORGE R. EVANISKO
PRIMARY EXAMINER

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